Many chronic diseases such as invasive cancers, inflammatory disorders, cardiovascular, or central nervous system diseases can have a significant impact on patient mobility as well as hindering the ability of caregivers to accompany patients to clinic visits. Hybrid and decentralized clinical trials can provide these patients the opportunity to participate in a clinical trial or even receive a treatment to which they would otherwise not have access.

Decentralized Clinical Trials (DCTs) are recognized as being an integrated and necessary part of the new clinical trial paradigm and require specific considerations in addition to those for site-based clinical trials.

Specific therapeutic area requirements prevent some clinical trials taking place away from a clinical site.

Additionally, the requirements of a particular patient population, protocol design specificities, or regulatory requirements also need to be considered.

- **The therapeutic area is not the only factor to consider when thinking through decentralizing clinical trials.** Rather, each trial should be appropriately designed to meet its objectives, should be patient-focused, and potential decentralized components should be assessed. The target patient population, the specifics of the treatment, the indication, the protocol procedures, and the regulatory requirements of the target countries all need to be factored in when determining whether a trial can be fully virtual, hybrid, or should be conducted as a traditional site-based trial.

Although fully virtual trials are expected to remain quite limited, it is possible that they may become more widespread for certain therapeutic areas such as rare diseases, mental health, central nervous system and neurodegenerative diseases that require patient populations that can't physically travel or don't live near a trial site.

- **Whilst technology evolves and adoption spreads, hybrid trials will likely be the norm**.
The beauty of hybrid clinical trials is their flexibility, taking into account patient preferences as much as protocol constraints. Hybrid trials offer the option of site visits for patients who still need the close care or

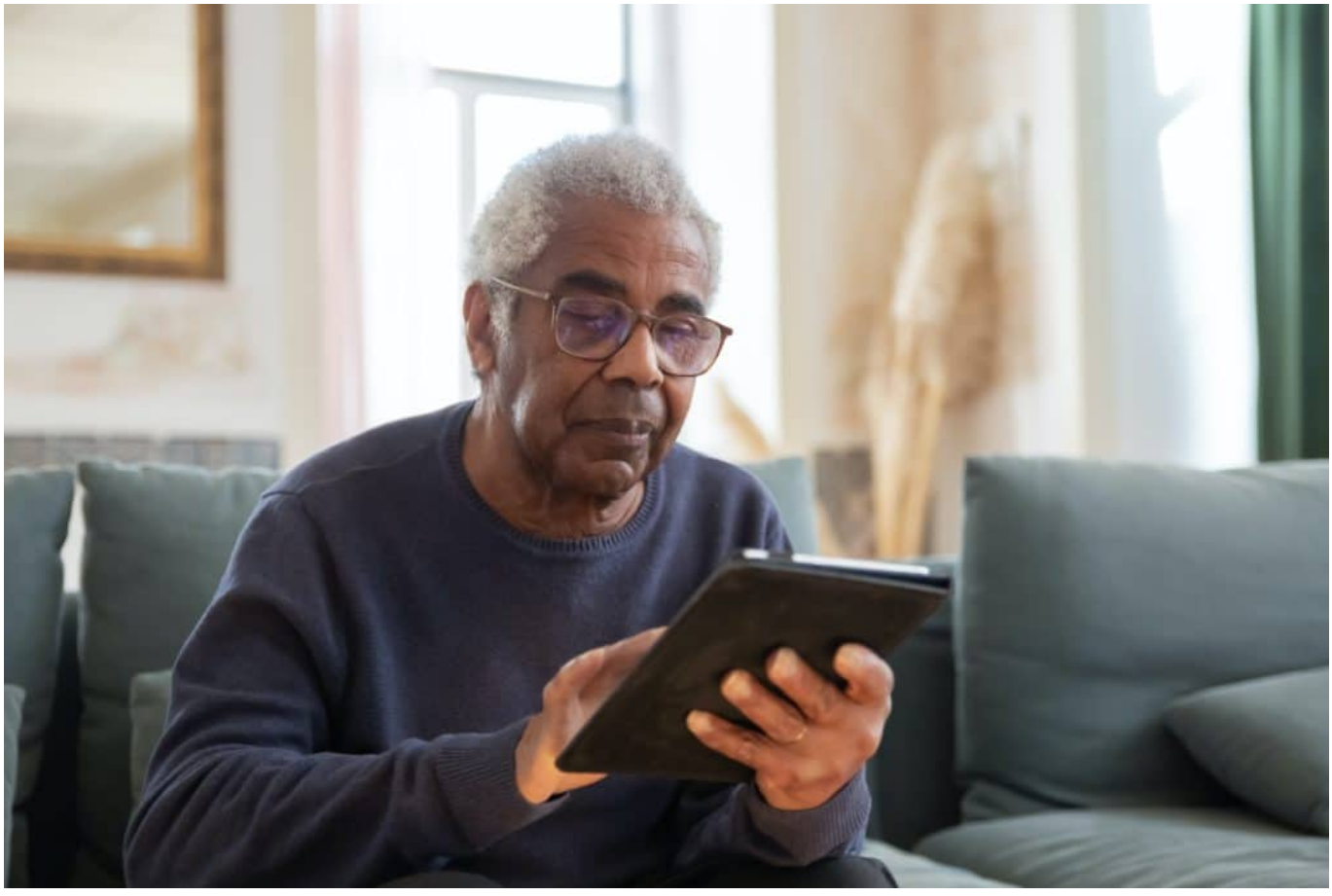
physical presence of their clinician, or those who have not yet adopted digital tools. Additionally, patients who value remote procedures can enjoy the comfort of televisits, ePRO, and eDiary data collection from home, blood sampling from a local laboratory or mobile nurse, and direct data capture and transmission via connected wearables.

Technological challenges must be tackled to move towards full adoption of DCTs

As for every innovation, the digitalization of clinical trials comes with its own share of technical challenges.

- **Decentralized clinical trials require significant integration of different systems**: aggregation and reconciliation of data from several sources, from any place at any time, is very complex. At the sponsor and vendor level, data management activities and requirements will grow in such a way that only strong data management services and well-trained teams will be able to process clinical trials data into relevant and meaningful clinical reports. It is necessary to ensure robust training for data management teams' and to reinforce quality controls. Proposing open platforms that allow the integration of systems is also key to broadening the spectrum of eCOA trials to other sources of data, while maintaining an easy-to-use solution.

- **Increasing remote components through hybrid trials and DCTs also leads to increased patient autonomy, which might not always be the best fit**. The REMOTE Study in overactive bladder disease, launched in 2011, was entirely home-based and had to stop early after failing to recruit sufficient participants. However, it provided important information about **the need for greater participant support and better resourcing to handle questions**.



As patients at home use digital tools in an unsupervised way, it is likely that helpdesk and support services will have to be adapted. Clinical teams will benefit from working with partners who can offer components of DCTs

together with close monitoring of patient needs. Additionally, partners will need to be able to provide a platform solution with multiple aspects, including increased support services and adapted back-up strategies, and will need not to rely wholly on technology to ensure that the study conduct flows easily.

- **Sites readiness is also a factor that might drive the implementation of decentralized components.** Although some sites have quickly adopted new technologies during the pandemic, others will need more time to become fully ready. Despite the time savings and the reduction in study site staff burden that may result from the decrease in site visits, additional complexities are generated by the numerous new technologies, the training requirements, and the evolution of site infrastructure. The clinical trials industry still has to improve **training material, site support and site infrastructure, and ensure that close collaboration is established between the monitoring team and site staff ahead of the start of a clinical trial.**

Regulatory & data privacy constraints are evolving, but differences between countries increase worldwide challenges for the implementation of clinical trials

The clinical trial industry has been slow to adopt decentralization and until recently, there was little regulation to help the implementation of remote components to clinical trials.

The regulatory landscape evolves continually, but not all regulatory agencies evolve in the same way or at the same pace, which adds complexity for launching DCTs in a wide range of countries. Teams will have to adapt their DCT strategy according to the national laws of the countries where the trial is planned, and promote hybrid strategies that will allow sites in the more traditional countries to still contribute to clinical trials whilst their regulations still need to evolve.

Implementing decentralized components will also mean that the study patients will be in direct contact with an increased number of people and systems. Data privacy concerns will have to be discussed with study teams and safeguards must be in place. This concern can become more significant when Bring Your Own Device (BYOD) is used to support decentralized clinical trials, but relevant security controls can be implemented within the solution.

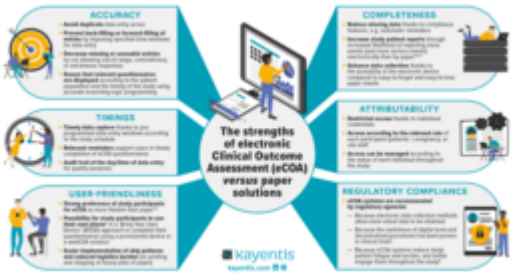
The FDA recommendation to use remote tools when an in-person site visit is not possible is as a strong driver of regulatory evolution. In situations when a patient is unable to travel to a trial site to provide informed consent, the FDA approves the use of an electronic consent form. Additionally, the use of clinical outcome assessments (COAs) is increasingly recommended to support and enhance patient centricity and diversity in clinical trials.

The EMA recently issued a Guideline on computerised systems and electronic data in clinical trials that should also provide a solid basis for the use of multiple digital technologies in clinical trials.

As the industry becomes increasingly comfortable and knowledgeable about DCTs, this new model will become more mainstream. However, several challenges still remain: protocol specificities will persist whilst technical challenges and clinical staff readiness will evolve. Dealing with data privacy and security rules, for which regulatory bodies remain the ultimate guarantor, will be key. To meet these challenges while keeping patient needs in mind, clinical trial sites and industry stakeholders will need to create a more flexible environment for patient-centric clinical trials.

Discover the 3 good reasons to adopt Decentralized Clinical Trials

Learn more:



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